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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,694	05/22/2000	Anne Sorensen	Novo-029	3706
23650	7590	01/11/2005	EXAMINER	
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			HON, SOW FUN	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/577,694

Applicant(s)

SORENSEN ET AL.

Examiner

Sow-Fun Hon

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 63-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/18/04 has been entered.

### ***Withdrawn Rejections***

2. The rejections of claims 1-62 in the previous Office action have been withdrawn due to cancellation of said claims.

### ***Claim Objections***

3. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). The second claim 66, or claim 66', should have been numbered claim 67.

Misnumbered claims 66'-75 been renumbered 67-76.

*New Rejections**Claim Rejections - 35 USC § 103*

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 66'-75 been renumbered 67-76.
5. Claims 63-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai (US 4,444,330).

Regarding claims 63, 67-68, 73, Kasai teaches a stopper which comprises an injection-mouldable blend of 30 to 90 weight % butyl based rubber and up to 30 weight % polyolefin (column 1, lines 45-55) which overlaps the combination of the claimed range of 70-90 % by weight of butyl rubber and 30-10 % by weight of polyolefin (claims 63, 73); and the narrower one of 75-87 % butyl based rubber and 13-25 % by weight of polyolefin (claim 67).

Kasai teaches that the polyolefin is polypropylene or polyethylene, added to improve mouldability (column 1, lines 60-65) (claim 68). Polypropylene and polyethylene are inherently not elastomers, as defined by Applicant's specification (page 5, lines 30-35 and page 8, lines 1-5).

Kasai teaches that the butyl rubber alone is subject to permanent set and cannot provide a stopper for hermetically sealing a medical container (column 2, lines 30-40) thus teaching that a stopper made from a combination of the butyl rubber and another component provides for a hermetically sealed container resulting in a reduced leakage of substances compared to a stopper made from butyl rubber alone.

Regarding claim 64-66, Kasai teaches that the butyl rubber is blended with up to 30 % polypropylene or polyethylene (column 1, lines 45-55), the blend is homogenized

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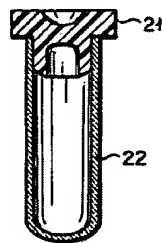
with heating (kneaded in mixer at 150 °C to 250 °C), and the stopper is injection moulded (column 3, lines 55-65). Injection moulding requires the blend to be fluid, thus injection moulding at 250 °C means that the thermoplastic polypropylene or polyethylene is in the melt. Hence the composition and process steps of stopper manufacture are similar to those described in Applicant's specification (page 2, lines 25-30). Therefore a hardness of 40-80 Shore A (claim 64), of 45-75 Shore A (claim 65), or of 65-75 Shore A (claim 66) is the result of routine experimentation by one of ordinary skill in the art at the time the invention was made, in order to obtain the desired stopper performance.

Regarding claims 69-70, the butyl-based rubber is a halogenated one (column 1, lines 50-55) such as a bromobutyl rubber (column 2, line 65).

Regarding claim 71, the butyl-based rubber is at least partially crosslinked (column 1, lines 50-55).

Regarding claim 72, Fig. 5 below shows that the stopper 21 has a substantially circular cross-section.

F I G. 5



Regarding claims 73-74, Kasai teaches a medical container with non-flexible (hard) walls (column 1, lines 10-15). Fig. 5 above shows that the container 22 comprises a distal and a proximal end, and at least one wall defining an interior space for storing liquid blood (column 5, lines 40-50). The term "medical container" means that the

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contents can be liquid medicament such as liquid infusion solution (column 1, lines 10-15).

Regarding claim 75, Kasai et al. provides an example of the process comprising mixing the butyl rubber and the thermoplastic polymer to form a stopper material, via heating (kneaded with a mixer) at 150 to 250 °C to pelletize them and then injection moulded at preferably 200 to 220 °C to form the stopper (column 3, lines 55-60). Since injection moulding is normally carried out at temperatures above the melting point of the injection moulding material, and the pelletizing stage above can use the same temperature range at which the injection molding is conducted (200 to 220 °C is within the pelletizing temperature range of 150 to 250 °C), the pelletizing stage conducts the three steps of heating the butyl based rubber, melting the thermoplastic polymer and homogenizing the material.

6. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai as applied to claims 63-74 above, and further in view of Rheude (US 2,507,680).

Kasai has been discussed above, and fails to teach a rod, or a rod moulded onto the stopper by the means of two-component injection moulding.

Rheude teaches a stopper for a container (bottle) which has a pusher rod 6 (column 2, lines 1-5). It can be seen in Fig 3 that the pusher rod results in the stopper being completely inserted into the neck of the container.

Anyone who has tried to shove a rubber stopper into a bottle neck knows how difficult it is to push it in completely. Rheude has shown that it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have attached a

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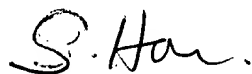
pusher rod to the stopper of Kasai, in order to facilitate insertion of the stopper into the neck of the container.

It would then have been an obvious variation to one of ordinary skill in the art at the time the invention was made, to have moulded the rod of Rheude onto the stopper during the injection moulding step in the process of Kasai, which step would then have been termed two component injection moulding.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sow-Fun Hon

